

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

EXELIXIS, INC.,)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. 19-2017-RGA-SRF
)	
MSN LABORATORIES PRIVATE)	
LIMITED and MSN)	
PHARMACEUTICALS, INC.,)	
)	
Defendants.)	

ORDER

At Wilmington this **14th** day of **July, 2021**, the court having considered Plaintiff's discovery dispute letter submission seeking a protective order against disclosure of Plaintiff's confidential information to Dr. Kondal Reddy Bairy (D.I. 157), and Defendants' letter submission in response (D.I. 159), IT IS HEREBY ORDERED THAT Plaintiff's requested relief is DENIED without prejudice for the following reasons:

1. Background. On December 13, 2019, the court entered the parties' proposed protective order in the above-captioned matter. (D.I. 12) The protective order defines the term "Confidential Information" to include "any form of trade secret or other confidential research, development, or commercial information within the meaning of Fed. R. Civ. P. 26(c)(1)(G)." (D.I. 159, Ex. 2 at ¶ 2A) Plaintiff has designated as "Confidential Information" its highly proprietary manufacturing process for cabozantinib-(s)-malate and the controls it employs to ensure the polymorphic form of cabozantinib-(s)-malate allegedly used in the accused product does not convert to another form. (D.I. 157 at 1) Individuals with access to confidential information under the protective order are limited to two in-house attorneys or legal department personnel per side, as well as their support staff. (D.I. 159, Ex. 2 at ¶ 11B)

2. Legal Standard. Generally, a party may obtain discovery “regarding any nonprivileged matter that is relevant to any party’s claim or defense and proportional to the needs of the case.” Fed. R. Civ. P. 26(b)(1). Under Rule 26(c)(1), the court may limit the scope of discovery by restricting access to confidential or trade secret information if there is “an unacceptable opportunity for inadvertent disclosure.” Fed. R. Civ. P. 26(c)(1)(G); *U.S. Steel Corp. v. United States*, 730 F.2d 1465, 1468 (Fed. Cir. 1984). The party requesting the protective order must show that “good cause” exists. Fed. R. Civ. P. 26(c)(1). “Good cause is established on a showing that disclosure will work a clearly defined and serious injury to the party seeking closure.” *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786 (3d Cir. 1994) (internal quotations omitted). “Broad allegations of harm, unsubstantiated by specific examples . . . will not suffice.” *Glenmede Trust Co. v. Thompson*, 56 F.3d 476, 483 (3d Cir. 1995). Courts have broad discretion in granting protective orders. *See Monolithic Power Sys., Inc. v. Intersil Corp.*, C.A. No. 16-1125-LPS, 2018 WL 6113465, at *1 (D. Del. Nov. 19, 2018).

3. Analysis. As a preliminary matter, the parties dispute whether Dr. Bairy qualifies as “in-house attorneys or legal department personnel” with access to confidential information under paragraph 11 of the protective order. (D.I. 159, Ex. 2 at ¶ 11) Dr. Bairy is not an attorney, and Defendants have no in-house legal counsel to oversee this litigation. (D.I. 157, Ex. C at 4:25-5:8) Regardless of whether Dr. Bairy meets the description of “legal department personnel,” the balance of factors weighs in favor of allowing Dr. Bairy access to Plaintiff’s confidential information. Otherwise, Defendants would have no employees eligible to review Plaintiff’s confidential information. (*Id.*)

4. Plaintiff contends that Dr. Bairy should not have access to Plaintiff’s confidential information because he serves as a competitive decision-maker for Defendants. (D.I. 157 at 2-3)

Courts routinely find that the risk of inadvertent disclosure is higher in situations involving a competitive decision-maker, and competitive decision-makers should therefore not generally be given access to confidential information. See *In re Deutsche Bank Trust Co. Americas*, 605 F.3d 1373, 1378 (Fed. Cir. 2010) (“[T]he counsel-by-counsel determination should turn on the extent to which counsel is involved in ‘competitive decisionmaking’ with its client.”). But the record before the court does not support a conclusion that Dr. Bairy is a competitive decision-maker.

5. First, Dr. Bairy confirms in a sworn declaration that he is not involved in the research and development of the accused ANDA product. (D.I. 159, Ex. 1 at ¶¶ 6-7) In this regard, the facts before the court are distinguishable from the cases relied upon by Plaintiff. See *SafeFlight Instrument Corp. v. Sundstrand Data Control Inc.*, 682 F. Supp. 20, 22 (D. Del. 1988) (rejecting plaintiff’s attempt to designate company president as in-house expert witness with access to defendant’s confidential information despite involvement in research and development); *R.R. Donnelley & Sons Co. v. Quark, Inc.*, C.A. No. 06-032-JJF, 2007 WL 61885, at *2 (D. Del. Jan. 4, 2007) (denying access to corporate officer engaged in supervising research and development).


6. Next, Plaintiff cites Dr. Bairy’s designation as Defendants’ 30(b)(6) witness on various competitive topics regarding product development and the ANDA submission. (D.I. 157 at 3) But in his role as a 30(b)(6) witness, Dr. Bairy was obligated to “testify about information known or reasonably available to the organization.” Fed. R. Civ. P. 30(b)(6). Dr. Bairy’s designation on these topics does not automatically support a conclusion that he personally participated in the development of the accused product. See *British Telecommc’ns PLC v. IAC/Interactivecorp*, C.A. No. 18-366-WCB, 2020 WL 1043974, at *6 (D. Del. Mar. 4, 2020) (acknowledging that 30(b)(6) witnesses must take steps “to acquire knowledge in preparation for

the deposition.”). Likewise, Dr. Bairy’s testimony that he regularly communicates with the research and development teams working on the accused product does not establish that he himself is directly involved in the research and development process. (D.I. 157, Ex. A at 25:12-26:24; 31:8-32:13; 33:5-34:12; 58:10-14) Instead, Dr. Bairy’s deposition testimony confirms that his role for Defendants was limited to ancillary communications in FDA-related matters, including overseeing all regulatory submissions from India. (*Id.* at 56:17-57:2, 137:1-141:3; D.I. 159, Ex. 1 at ¶ 8) These facts do not support a conclusion that Dr. Bairy is a competitive decision-maker. (D.I. 157, Ex. C at 12:18-18:6) (describing a limited chance for misuse of confidential information in subsequent communications with the FDA because the ANDA process was already well underway).

7. In balancing the risk of inadvertent disclosure or misuse against the potential harm to Defendants from restrictions imposed on Defendants’ access to information, I find that the factual considerations and relevant case authorities weigh in favor of allowing Dr. Bairy to have access to Plaintiff’s confidential information, subject to the terms of the protective order. *Deutsche Bank*, 605 F.3d at 1380 (noting that the court has broad discretion to decide the degree of protection in balancing the risk of inadvertent disclosure or misuse against the potential harm to the opposing party from restricted access to information). Because Dr. Bairy is not a competitive decision-maker, the risk of inadvertent disclosure is low. In contrast, the harm to Defendants from Plaintiff’s proposed restrictions on this information is significant. *See R.R. Donnelley*, 2007 WL 61885, at *1 (noting that high risk of inadvertent disclosure may be offset if “in-house counsel’s lack of access would impede a party’s ability to litigate through outside counsel.”). The record establishes that Defendants have no in-house counsel, and Dr. Bairy is the only employee coordinating on this litigation with outside counsel. (D.I. 159, Ex. 1 at ¶¶ 2-

3) Under similar circumstances involving the same defendant, courts in this district have permitted access to a non-attorney employee. (D.I. 157, Ex. C)

8. Conclusion. IT IS ORDERED that Plaintiff's request for a protective order is DENIED, and Dr. Bairy may have access to Plaintiff's confidential information under the terms of the protective order after executing the "Undertaking" substantially in the form of Exhibit A to the protective order. (D.I. 159-2 at 22; Ex. 2 at ¶ 12B) IT IS FURTHER ORDERED that the combined discovery dispute and status teleconference scheduled for July 14, 2021 at 2:00 p.m. is CANCELLED. If the parties have matters requiring the court's attention, a joint status report identifying those matters may be filed on or before **July 16, 2021**.



Sherry R. Fallon
United States Magistrate Judge